

### Priority publications : EHCSS-JLI

	Estimated Submission Date	Author/Coordinator
<i>Non-Clinical</i>		
- <b>Smoke chemistry</b>		
FTC, Mass., HC, Topography-based	3/03	Roemer <sup>19</sup>
- <b>Cytotoxicity</b>	3/03	Roemer <sup>19</sup>
- <b>Genotoxicity</b>	3/03	Roemer <sup>19</sup>
- <b>Rodent inhalation</b>		
Acceptability	3/03	Roemer <sup>19</sup>
Lung Inflammation	3/03	Roemer <sup>19</sup>
Larynx analysis	4/03	Roemer <sup>39</sup>
Particle Deposition	4/03	Roemer <sup>39</sup>
<i>Clinical</i>		
- <b>Controlled exposure</b>		
Exposure biomarkers	<del>4/03</del> 7/03	Roethig <sup>39</sup>
Larynx examination	<del>4/03</del> 7/03	Roethig <sup>39</sup>
Topography	<del>4/03</del> , 6(?) /03	Roethig <sup>39</sup> , Roethig/Roemer <sup>42</sup>
- <b>Menthol</b>	9/03	Roethig <sup>41</sup>
- <b>Unrestricted exposure</b> ( <i>from 12 month data?</i> )		
Exposure biomarkers	(3/04)	Roethig <sup>40</sup>
Larynx examination	(3/04)	Roethig <sup>40</sup>
3-month interim data	<del>4/03</del> 7/03	Roethig <sup>39</sup>
<i>Surveillance Plan</i>		
Behavioral	2/03 (poster), post-launch/03	Roethig <sup>32, 31</sup>
<i>Risk Assessment</i>		
Cancer/non-cancer risks	12/02, 3/03 (poster)	Hausmann <sup>35, 33</sup>
Brand Study	12/02	Reininghaus <sup>38</sup>

<i>Methodology</i>		
- <b>Biomarkers</b>		
3-hydroxypropylmercapturic acid (HPMA)	3(?) /03	Roethig <sup>43</sup>

November 21, 2002

Communication plan EHCSS-JLI DRAFT CONFIDENTIAL

1

PM3006737090

# ***Appendix I: List of publications/presentations***

- 1 Tewes, F.J.; Vettel, D.J.; Heil, M.; Solana, R.P., "Discrimination of cigarette mainstream smoke with the neutral red uptake cytotoxicity assay". Presentation at the **Society of Toxicology, 1998.**
- 2 Voncken, P.; Gerstenberg, B.; Rustemeier, K.; Stabbert, R.; Patskan, G.J.; Haussmann, H.J., "Chemical analysis of selected cigarette mainstream smoke constituents for comparative product integrity testing". Presentation at the **Tobacco Science Research Conference, 1998.**
- 3 Roemer, E.; Meisgen, T.J.; Tewes, F.J.; Solana, R.P., "Discrimination of cigarette mainstream smoke condensates with the Salmonella reverse mutation assay". Presentation at the **Society of Toxicology, 1998.**
- 4 Vanscheeuwijck, P.M.; Ansket, E.A.; Teredesai, A.; Solana, R.P., "Equi-effect design for subchronic inhalation toxicity studies comparing conventional and novel cigarette prototypes". Presentation at the **Society of Toxicology, 1998.**
- 5 Terpstra, P.M.; Reininghaus, W.; Solana, R.P., "Evaluation of an electrically heated cigarette". Presentation at the **Society of Toxicology, 1998.**
- 6 Buchhalter, A.R.; Eissenberg, T., "Reduced CO boost produced in humans smoking a novel smoking system". Presented at the **Society for Research on Nicotine and Tobacco, 1999.**
- 7 Gerstenberg, B.; Stinn, W.; Reininghaus, W., "Comparison of environmental tobacco smoke from an electrically heated and a conventional cigarette". Presentation at **Tobacco Science Research Conference, 2000.**
- 8 Rustemeier, K.; Patskan, G.; Haussmann, H.J., "The influence of a modified puffing regimen on the yields of smoke constituents from electrically heated and conventional research cigarettes". Presentation at the **Society of Toxicology, 2000.**
- 9 Terpstra, P.M.; Reininghaus, W., "Chemical and biological evaluation of smoke from an electrically heated cigarette". Presentation at **Asian Society of Toxicology, 2000.**
- 10 Buchhalter, A.R.; Eissenberg, T., "Preliminary evaluation of a novel smoking system: effects on subjective and physiological measures and on smoking behavior". **Nicotine & Tobacco Research 2: 39-43; 2000.**
- 11 Stabbert, R.; Schaefer, K.H.; Biefel, C.; Rustemeier, K., "Analysis of aromatic amines in cigarette". Presentation at the **Tobacco Science Research Conference, 2001.**
- 12 Gerstenberg, B.; Stinn, W.; Reininghaus, W., "Comparison of environmental tobacco smoke from an electrically heated and a conventional cigarette". Presentation at **Society of Toxicology, 2001.**

# ***Appendix I: List of publications/presentations***

- 13 Breland, A.; Buchhalter, A.; Evans, S.; Eissenberg, T., "Comparison of the withdrawal suppression, physiological effects, and nicotine delivery of two novel smoking systems". Presented at the **Society for Research on Nicotine and Tobacco, 2001**.
- 14 Buchhalter, A.R.; Schrinel, L.; Eissenberg, T., "Withdrawal-suppressing effects of a novel smoking system: comparison with own brand, not own brand, and de-nicotinized cigarettes". **Nicotine & Tobacco Research** 3: 111-118; **2001**.
- 15 Breland, A.; Buchhalter, A.; Evans, S.; Eissenberg, T., "Laboratory evaluation of the withdrawal suppression, physiological effects, carbon monoxide boost, and nicotine delivery of two novel smoking systems". Proceedings, 63rd Annual Scientific Meeting College on Problems of Drug Dependence S19 (paper 64), 2001. Presented at the 63rd annual scientific meeting of the **College on Problems of Drug Dependence, 2001**.
- 16 Roethig, H.J.; Kinser, R.; Nelson, B.L.; Lau, R.W., "Investigation of biomarker of exposure of adult smokers smoking electrically heated and conventional cigarettes". Presentation at the **Society for Research on Nicotine and Tobacco, 2002**.
- 17 Roethig, H.J.; Oey, J.; Nelson, B.L.; Walk, R.A., "Dose-response investigations of carboxy-hemoglobin of adult smokers smoking conventional and electrically heated cigarettes". Presentation at the **Society of Toxicology, 2002**.
- 18 Roemer, E.; Vanscheeuwijck, P.; Elves, R.G.; Fournier, J., "Ammonium magnesium phosphate in the paper wrapper of an electrically heated cigarette reduces the biological activity of the resulting smoke". Presentation at the **Society of Toxicology 2002**.
- 19 Planned manuscript by Mar 2003 on HYDRA AMP (Roemer):
  - rodent irritation, AMP paper, F-lighter, non-menthol
  - smoke chemistry, AMP paper, JLI Production lighter, menthol
  - smoke chemistry, AMP paper, JLI Bridging lighter, non-menthol
  - smoke chemistry, AMP paper, JLI Production lighter, non-menthol
  - cytotoxicity, AMP paper, JLI Bridging lighter, non-menthol
  - genotoxicity, AMP paper, JLI Bridging lighter, non-menthol.
- 20 Patskan, G.; Reininghaus, W., "Toxicological Evaluation of an Electrically Heated Cigarette Part 1: Overview of Technical Concepts and Summary of Findings", submitted to **Journal of Applied Toxicology, Apr 2002**.

## ***Appendix I: List of publications/presentations***

- 21 Stabbert, R.; Voncken, P.; Rustemeier, K.; Haussmann, H.J.; Roemer, E.; Schaffernicht, H.; Patskan, G., "Toxicological Evaluation of an Electrically Heated Cigarette Part 2: Chemical Composition of Mainstream Smoke", submitted to **Journal of Applied Toxicology**, **Apr 2002**.
- 22 Tewes, F.J.; Meisgen, T.J.; Veltel, D.J.; Roemer, E.; Patskan, G., "Toxicological Evaluation of an Electrically Heated Cigarette. Part 3: Genotoxicity and Cytotoxicity of Mainstream Smoke", submitted to **Journal of Applied Toxicology**, **Apr 2002**.
- 23 Terpstra, P.M.; Teredesai, A.; Verbeeck, J.; Schepers, G.; Radtke, F.; Kuhl, P.; Gomm, W.; Anskett, E.; Patskan, G., "Toxicological Evaluation of an Electrically Heated Cigarette. Part 4: Subchronic Inhalation Toxicology", submitted to **Journal of Applied Toxicology**, **Apr 2002**.
- 24 Roethig, H.J.; Oey, J.; Nelson, B.L.; Walk, R.A., "Investigation of carboxy-hemoglobin of adult smokers of conventional cigarettes and an electrically heated cigarette (Oasis)". Presented at the 29th Annual Meeting of the Japanese Society of Toxicology, Nagoya Congress Center, Japan, **Jun 2002**.
- 25 Lau, R.W.; Hirnikel, D.J.; Roethig, H.J., "Environmental tobacco smoke from smoking conventional and electrically heated cigarettes". Presented at the 2002 annual meeting of **ISEA/SEE**, **August 2002**.
- 26 Planned manuscript on E4 controlled exposure study: study design, exposure biomarkers & mitigation strategy, Feb 2003. (Roethig)
- 27 Roethig, H.J.; Kinser, R.D.; Nelson, B.L.; Oey, J.; Wang, N., "Short term clinical exposure evaluation of conventional and electrically heated cigarettes", to be presented at the **American College of Clinical Pharmacology Annual Meeting**, **Sep, 2002**.
- 28 Planned manuscript on E4 controlled exposure study: cigarette burn time, Dec 2002. (Roethig)
- 29 Lau, R.W.; Hirnikel, D.J.; Roethig, H.J., "Comparison of environmental tobacco smoke (ETS) from conventional and electrically heated cigarettes". To be submitted to **Journal of Exposure Analysis and Environmental Epidemiology**, **Nov 2002**.
- 30 Planned manuscript on record exercise study, Dec 2003. (Roethig)
- 31 Planned manuscript on post marketing surveillance plan, post JLI launch - 2003. (Roethig)
- 32 Planned poster on post marketing surveillance plan, SRNT, Feb 2003 (Roethig)
- 33 Poster on risk assessment-based toxicological weighting of cigarette smoke constituents, to be submitted to **Society of Toxicology Meeting**, Mar 2003. (Haussmann)

## ***Appendix I: List of publications/presentations***

- 34 Poster on reduced biological activity of cigarettes with high capacity activated carbon filter, to be submitted to Society of Toxicology Meeting, Mar 2003. (Roemer)
- 35 Planned manuscript on toxicological weighting of cigarette smoke components, Dec 2002. (Hausmann)
- 36 Planned manuscript on cigarette chemistry of ammonia in relation to nicotine delivery. (Podraza)
- 37 Planned manuscript on chemical analysis of mainstream smoke from reference cigarettes and EHCSS under different smoking conditions, Feb 2003. (Roethig)
- 38 Planned manuscript on Grand Study, Dec 2002. (Reininghaus)
- 39 Planned manuscript on JLI controlled exposure study: with 3 month data from unrestricted exposure study, Apr 2003. (Roethig)
- 40 Planned manuscript on JLI unrestricted exposure study, Mar 2004. (Roethig)
- 41 Planned manuscript on JLI menthol controlled exposure study, Sep 2003. (Roethig)
- 42 Planned manuscript on smoking topography and smoke chemistry, 2003. (Roethig, Roemer)
- 43 Planned manuscript on analytical method of acrolein biomarker 3-hydropropylmercapturic acid (HPMA), Mar 2003 (tentative). (Roethig)

PM3006737094

November 21, 2002

Communication plan EHCSS-JLI DRAFT CONFIDENTIAL

5